

Cultured Whey
sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

5. (Once amended) The fully cooked, stabilized pasta composition of claim 2 further comprising a pasta filling or a pasta sauce, wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

6. (Once amended) The fully cooked, stabilized pasta composition of claim 3 further comprising a pasta filling or a pasta sauce, wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

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14. (Once amended) The method of claim 11, wherein the fully cooked, stabilized pasta composition further comprises a pasta filling or a pasta sauce and wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

15. (Once amended) The method of claim 12, wherein the fully cooked, stabilized pasta composition further comprises a pasta filling or a pasta sauce and wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

16. (Once amended) The method of claim 13, wherein the fully cooked, stabilized pasta composition further comprises a pasta filling or a pasta sauce and wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing

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whey used to prepare the pasta composition or a second nisin-containing cultured whey.

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24. (Once amended) The method of claim 21, wherein the fully cooked, stabilized pasta composition further comprises a pasta filling or a pasta sauce and wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

25. (Once amended) The method of claim 22, wherein the fully cooked, stabilized pasta composition further comprises a pasta filling or a pasta sauce and wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

26. (Once amended) The method of claim 23, wherein the fully cooked, stabilized pasta composition further comprises a pasta filling or a pasta sauce and wherein the pasta filling or pasta sauce is stabilized using the same nisin-containing whey used to prepare the pasta composition or a second nisin-containing cultured whey.

REMARKS

Applicants respectfully request reconsideration of the present application and claims in light of the amendments and remarks presented herein. Upon entry of the foregoing amended claims, Claims 4-6, 14-16, and 24-26 have been amended, and Claims 1-30 are pending. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with

Markings to Show Changes Made". No new matter has been added with the amendments.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1, 11, and 21 stand rejected under 35 U.S.C. §112, first paragraph. The Examiner asserts that the specification does not reasonably provide enablement for a product having shelf stability of "at least 120 days" at refrigeration temperature.

In order to make an enablement rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *See In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993) (An examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification that contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. *See* MPEP 2164.04. The pasta composition of the present invention was disclosed to be shelf stable for 120 days or longer in the specification (pg. 5, lines 19-23). The disclosure also describes the manner and process of making and using a product that is shelf stable for 120 days or longer. Thus, Applicants' claim to a product having shelf stability of "at least 120 days" at refrigeration temperature is sufficiently enabled under 35 U.S.C. §112, first paragraph.

Moreover, the use of "at least 120 days" with regard to the shelf stability at refrigeration temperature is a common and standard claim drafting technique. To limit the shelf life stability to "120 days" (as the Examiner may be suggesting) would unduly limit the claim since a shelf stability of, for example, 130 days, would certainly be considered within the scope of the present invention but might not be considered to fall

within the "120 days" limitation. Additionally, the use of such a limitation (i.e. "at least 120 days") allows the application to be filed within a timely manner. Applicants have, as the Examiner notes, demonstrated 120 day shelf life. But, as one skilled in the art would understand, the shelf life extends beyond the 120 days (to some unknown period). To require Applicants to continue the experiments further (perhaps for a considerable time period) would unduly delay filing of the application. Applicants have demonstrated a shelf life of "at least 120 days;" nothing more is required. Applicant respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-30 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserts that the term "high protein wheat flour" is indefinite. Applicants respectfully assert that, as used in the instant claims, the term "high protein wheat flour," and in particular the term "high," are not vague or indefinite, nor do they render the claims in question vague or indefinite. The specification explains that a flour having minimum average protein content of about 12 to about 13.5 weight percent (and more preferably about 13 to about 13.5 weight percent) should be used (specification pg. 9, lines 15-23). Thus, as defined in the specification, a "high protein wheat flour" is a wheat flour with an average protein content of about 12 to about 13.5 weight percent or higher. As a result, the meaning of the term "high protein wheat flour" is clear from the specification.

Claims 4-6, 14-16, and 24-26 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserts that the term "similar nisin-containing cultured whey" is indefinite. Although Applicants disagree that the phrase is indefinite, Claims 4-6, 14-16, and 24-26 have been amended to remove the term "similar" and more particularly point out and claim the invention.

Applicants respectfully submit that all rejections under 35 U.S.C. §112, second paragraph, have been overcome.

Rejections Under 35 U.S.C. §103(a)

Claims 1-30 stand rejected under 35 U.S.C. §103(a) as being obvious over Bajracharya et al. (U.S. Patent No. 6,001,405) in view of Taylor (U.S. Patent No. 4,597,972) and Nauth et al. (U.S. Patent No. 6,110,509).

Applicants respectfully submit that a *prima facie* case of obvious has not been established. All the elements of the claimed invention are not taught by the cited art.

The '405 patent discloses a process for the preparation of a pre-cooked filled pasta product. The disclosure of the '405 patent is limited to a pasta that "is not a 'ready to eat' pasta" but instead the pasta of the '405 patent "requires a short period of cooking and rehydration for consumption" (col. 1, lines 35-44). Additionally, the pasta composition of the '405 patent is partially dried, thus the need for rehydration prior to consumption (col. 2, lines 64-66). In contrast the present invention is directed to a fully cooked pasta composition that is of the warm and serve variety. The pasta composition of the present invention needs only to be heated to a suitable serving temperature before consumption (pg. 14, lines 21-23). The pasta composition does not need to be cooked by the consumer since it is already fully cooked when purchased (pg. 14, lines 23-25). The pasta of the present invention is fully hydrated and only requires warming before serving; the pasta composition does not require the cooking and rehydration required by the pasta disclosed in the '405 patent. Thus, the '405 patent does not disclose, nor does it make obvious, a fully cooked pasta composition of the warm and serve variety as claimed.

Additionally, to establish *prima facie* obviousness, there must be some specific suggestion or motivation in the prior art to modify the reference or to combine the teachings of the several applied references. See MPEP 2143 and 2143.01. The teaching or suggestion to make the claim combination must be found in the prior art, not in the Applicants' disclosure, see MPEP 2143, *citing In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991) or in an Examiner's unsupported assertion. There is no such teaching, suggestion, or motivation in the cited art for the addition of nisin, much less a nisin-containing why,

to the pasta composition of the present invention. The '972 patent teaches the addition of nisin to cheese (col. 2, lines 20-21), tomato products, cold meat products, wet fish systems (col. 2, lines 41-42), canned peas and beans, canned mushrooms, canned tomato products, and soups (col. 2, lines 47-48). The '509 patent¹ teaches the inclusion of nisin-containing whey in cream cheese. None of these references teach or suggest, or provide any motivation for, the use of nisin or nisin-containing whey in pasta-type products, much less in the fully cooked pasta composition of the present invention. The Examiner suggests that the "nisin as taught by Nauth et al. is advantageous to the Bajracharya et al. [composition] since the nisin is contained in the whey which will further increase the protein content of the pasta product; this further enhances the nutritious value of the product." This unsupported statement cannot provide the required motivation to combine the references as suggested by the Examiner. Last, there is not teaching or suggestion in the cited art that nisin, much less nisin-containing whey, could be incorporated into pasta products as provided by the present invention or that it could provide a shelf life of at least 120 days under refrigeration conditions.

As discussed above, the '405 patent does not disclose a fully cooked pasta that is of the warm and serve variety. Likewise, neither the '509 or the '972 patents disclose that nisin or nisin-containing whey can be used as an antibotulinal agent in warm and serve pasta compositions to achieve the shelf life under refrigeration conditions as provided by the present invention.

CONCLUSION

Applicants submit that the present amendments and remarks overcome all remaining rejections. In view of the foregoing amendments and remarks, Applicants

¹ Related applications (see p.4, lines 19-30) teach the use of nisin-containing whey in fermented dairy compositions, mayonnaise spreads, cooked meats, and cooked meat and vegetable compositions.